

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Division of Medical Products and Tobacco Program Operations Office of Medical Products and Tobacco Operations, U.S. Food and Drug Administration 12420 Parklawn Drive, ELEM-2032 Rockville, MD 20857 (301) 796-5521 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/5 - 11/15/2013
	FEI NUMBER 1011574

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: David P. Burney, Chief Operating Officer

FIRM NAME Greer Laboratories, Inc.	STREET ADDRESS 639 Nuway Circle NE (P.O. Box 800)
CITY, STATE AND ZIP CODE Lenoir, NC. 28645	TYPE OF ESTABLISHMENT INSPECTED Allergenic Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Product is not manufactured as described in the approved license application. For example:

A. Customers place orders for custom compounded lots, which are composed of a mixture of standardized/ non-standardized / (b) (4) / (b) (4) allergenic bulk extracts. The custom orders are not linked to specific patients. In 2012, (b) (4) Custom Mixed Lots were manufactured, which represents approximately (b) (4) of all lots produced.


B. An appropriately identified reserve sample(s), representative of each lot or batch of product is not retained and/ or stored under conditions consistent with product labeling and/or in the same immediate container-closure system. Specifically, reserve samples are not maintained for custom mixed lots. In addition, retain samples are not maintained for the final formulated bulk lot.

C. Filling technicians routinely decant or pipette the clear portion of bulk extract away from precipitated product. This is not an approved re-processing procedure and is performed without review/approval/tracking by the quality unit. SOP # PX04 requires that (b) (4) but this is not followed for this type of reprocessing.


D. Failure to perform an approved general safety test. Specifically, not all allergenic extract filling of more than (b) (4) vials are tested for General Safety. For custom mixed lots, from January to October 2013, there were approximately (b) (4) filled lots that were not tested for General Safety; and there were approximately (b) (4) filled custom filled lots not tested for General Safety in 2012. Standardized and non-standardized lots are also not all tested for General Safety. For example:

i. (b) (4) vials were manufactured of Candida Alibicans lot # 213813 on 09/21/2012. No General Safety test was performed on this vial lot. An adverse event report was received for this lot.

ii. (b) (4) vials were manufactured of Crab lot # GF12A02 on 09/26/2012. No General Safety test was performed on this lot.

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<p>iii. (b) vials were manufactured of Dandelion lot # 212334 on 09/12/2012. No General Safety test was performed on this lot.</p> <p>iv. (b) vials were manufactured of Standardized Kentucky Blue/June lot # 201436 on 04/03/2012. No General Safety test was performed.</p> <p>2. Laboratory controls do not include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure components and products conform to appropriate standards of identity, strength, quality and purity.</p> <p>A. Final bioburden test result for drug product, Modified Glycero Cocas lot # 216273, was too numerous to count (TNTC). The contaminants were identified as Brevibacillus brevis and Leifsonia aquatic. The lot was released on 12/06/2012 although there is no assurance that the bioburden load does not exceed the validated (b) (4) capabilities. The final QA Product Specification and Release form indicates that there were no deviations encountered for this lot although a laboratory investigation and General Quality Investigation was also conducted for the bioburden out of limit (OOL).</p> <p>B. General Safety Testing for Custom Mixed lot AASC Weed-1 Mix A lot # 208189 failed on 07/20/2012. The investigation concluded that (b) (4) in the product administered via intraperitoneal route was the root cause for the (b) (4) test failure. This firm has not validated the impact of full dosage, reduced dosage, route of administration for allergenic extract lots that contain (b) (4) concentrations other than (b) (4).</p> <p>C. The appearance of bulk extract and filled products are not documented and there is no way to determine if changes to appearance have occurred since release. For example:</p> <p>i. On 11/08/2013, two allergenic bulk extract lots released for filling operations were found in the cold storage very with a very cloudy appearance.</p> <p>ii. Two separate complaints were received indicating that Whole Wheat lot # 223820 did not have the same appearance as previous Whole Wheat lots received.</p> <p>3. Out of specification test results are invalidated without determining a definitive laboratory error. There were 10 sterility failure investigations conducted in 2012 and 2013 for drug products and allergenic extract lots. 8 of the 10 investigations concluded "laboratory error" was the reason for the sterility failure and 4 lots were retested and</p>			
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released based on the conclusion of Laboratory error. For example:


A. Positive sterility test result on (b) (4) for Sterile Diluent for Allergenic Extract with (b) (4) lot # 190874 was invalidated without determining a laboratory error. (b) (4) allergenic extract lots and (b) (4) drug product lots were tested on the same day, but only lot # 190874 tested positive. The negative controls were negative and no environmental/personnel monitoring excursions occurred in the Class 100 Sterility Suite during the test day (b) (4). The laboratory investigation concluded "Conclusive lab error. Repeat sterility test may be performed", indicating that the sample and not the lot was contaminated. The lot was released and shipping started on 12/14/2011.

B. Allergenic extract product, Cantaloupe/Muskmelon (b) (4) Bulk lot # 205992 tested positive for contamination on (b) (4). The contaminating organism was identified as Chryseobacterium indologenes, a gram negative rod. No error was identified from the laboratory investigation, no other positive results, and no environmental/personnel monitoring excursions occurred in the laboratory on the test day. Non-viable excursions were noted in the filling suites. The investigation concluded "Conclusive lab error. Repeat sterility test may be performed", indicating that the sample and not the lot was contaminated. The lot was released on 10/01/2012.

4. There is no assurance that required testing is performed on samples that are representative of the final released product. Specifically, there is no defined speed or time for mixing custom orders that can contain as much as (b) (4) different (b) (4) and (b) (4) allergenic extract lots. The mixing step requires a technician to (b) (4). The mixing step has not been validated to assure a uniform final formulated bulk.

5. Facilities designed to prevent contamination or mix-ups are deficient regarding aseptic processing of drug products. Specifically,

A. Manufacturing operations for allergenic extracts requires first aseptically formulating the final bulk followed by aseptic filling into vials. (b) (4) allergenic extract lots can be formulated and filled in one day (b) (4). (b) (4) technicians perform formulation and fill of individual lots with no clear separation of activities to prevent mix-ups.

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B. For (b) (4) fills of allergenic extracts, the vial volume check requires (b) (4). At the end of fill, if there are more vials left to be filled, (b) (4). This activity is not simulated during media fill.

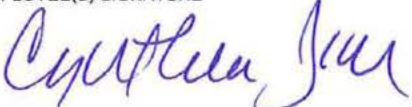
C. The (b) (4) filling operations of allergenic extracts allow that if a bulk container contains visible particulates, the clear portion of the bulk is drawn out with a pipette or decanted into another bottle. This reprocessing of product is not properly documented and not adequately simulated during media fill operations.

D. Failure to provide convenient handwashing facilities for personnel. Specifically, personnel going into the sterile filling suite, and the sterility testing suite share the same gowning room. Personnel have to gown and wash their hands and subsequently enter a common nonclassified corridor before entering another gowning room to complete gowning prior to going into the sterile suites. The majority of sterility test failures were determined to be contamination of the samples by personnel in the sterile testing suite.

E. The air is not monitored for viable organisms throughout the filling operation. Only (b) (4) active (b) (4) air sample per location is taken in the morning and another taken in the afternoon. There are no settle plates used to monitor the environment. In one day's operation, (b) (4) different lots can be filled. (b) (4).

F. Classified clean rooms designed to prevent contamination are deficient regarding aseptic processing of drug products. There is no assurance that standard allergenics and/or sterile diluents manufactured in Bldg. # (b) (4), room (b) (4) (aseptic filling suite) was under control and maintained in a sterile environment. QA Investigations #QAINV 12-015 and #QAINV 13-010 "General Quality Investigations for Pest Control Excursions" disclosed numerous investigations ranging from 2011- 2013 reporting various types of live/dead insects in the aseptic areas during and after filling operations. The root cause of identifying the point of entry has not been established.

G. Buildings used in the manufacture processing, packing, or holding of drug products are not free of infestation by rodents, birds, insects, and other vermin. Specifically, two different QA Investigations # QAINV 12-015 (closed 12/13/2012) and # QAINV 13- 010 "General Quality Investigations for Pest Control Excursions" were conducted in response to an alarming trend of living insect sightings primarily in Bldg. # (b) (4) aseptic filling areas

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during and after aseptic operations. Pest control logs also verified various types of pests in other classified and unclassified areas. QA Investigation # QAINV 13- 010 is still open.

6. Failure to conduct investigations into unexplained discrepancies or the failure of a batch or any of its components to meet specifications: For example,


A. The manufacturing investigation is inadequate for the following lots that failed the general safety tests. The lots were rejected but root cause was not determined, product impact not assessed, and corrective/preventive actions not implemented.

- i. Water Hemp lot # 227727 failed on 06/20/2013;
- ii. Green Pea lot # 230883 failed on 05/16/2013;
- iii. Palmer's Amaranth lot # 218797 failed on 02/11/2013;
- iv. Water Hemp lot # 220482 failed on 02/25/2013; and
- v. Greer Stock Pigweed Mix lot # 193904 which failed on 01/31/2012.

B. The manufacturing investigations are inadequate for complaints received regarding allergenic extracts. Investigations do not detail the following information as required by SOP # GN021, Service and Product Complaint Handling: review of batch records; review of retention samples; review of other associated lots in inventory; review of stability data; review of complaint history and trending; investigation results and corrective/preventive actions. For example: Adverse event report # 12/026 was received 10/31/2012 regarding Custom Mix FAC Comprehensive Mix lot # 202479. The patient experienced urticaria, angioedema, wheezing, dyspnea, and anaphylaxis after use of this custom mix as Sublingual Immunotherapy (SLIT) drops. Lot # 202479 had approximately 20 different Greer allergenic extract components yet there was no detail provided for the batch record review, trending or lot/product, deviations, and OOL's.

C. Investigations regarding pest control excursions in aseptic fill areas.

i. There is a failure to thoroughly review investigations regarding microbiological contamination of drug products purporting to be sterile. Specifically, Deviation CY12135 was initiated 08/10/2012, due to an aseptic operator discovering a dead insect in room (b) (4) (aseptic filling suite). The drugs product department was still manufacturing products on the west side of the same aseptic filling suite when the insect was discovered. The

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investigation stated that incident was isolated; however QA Investigation #QAINV 12-015 "General Quality Investigations for Pest Control Excursions" demonstrated an upward trend of pest control excursions from previous deviations dating back to June 2011. The type of insect was not identified and the point of entry was not identified. A routine sanitization was conducted in the aseptic fill suite after the insect was discovered. The product was initially placed on hold and then released after environmental monitoring records were evaluated.

ii. Written records are not always made of investigations into aseptic contamination events and do not include the conclusions and follow-up. Specifically Deviation CY12142 was initiated 08/16/2012, due to a (b) (4) environmental service technician discovering an insect on the floor in room (b) (4) (aseptic filling suite) next to the weighing station. This incident occurred while the environmental services were performing their nightly cleaning and sanitization. The insect was not identified and the environmental service technicians performed a double sanitization in the clean room. A point of entry for the insect was not identified. QA Investigation #QAINV 13-010 "General Quality Investigations for Pest Control Excursions" documented an additional five (5) separate similar insect observation incidents occurred on 07/23, 08/05/, 08/28, 08/31 and 09/24/2013 in the aseptic fill area; however they were logged in the "Pest Sighting Log" and did not generate a deviation. The "Pest Control Log" is reviewed by Quality Assurance on a (b) (4) basis.

iii. Employees did not follow appropriate written procedures that describe the reporting of aseptic related incidents. Specifically, employees are instructed to report any anomalies during aseptic operations in the "Aseptic Fill Incident" and/or "Pest Control" logs. The firm has experienced an increasing trend with insect infestation during or after aseptic fill operations. Log book entries have not coincided when contaminating events (i.e., insects) have occurred, due to aseptic operators neglecting to record the events. Quality Assurance is supposed to review and evaluate each incident accordingly.

7. Written reports of investigations of adverse reactions, including conclusions and follow up, are not prepared and maintained. Specifically,

A. On 09/10/2013, this firm received report of death of a (b) (6) patient following administration of allergenic extracts supplied by Greer. No investigation report had been generated at the time of this inspection although SOP # GN021 requires, "investigation shall be completed within (b) (4) days" and extension had not been approved by QA.

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B. On 12/13/2012, adverse event report # 12-029 that a (b) (6) patient experience severe swelling under tongue after administering allergenic extract manufactured by Greer, was not investigated.

C. On 11/30/2012, adverse event report # 12-028 that a patient experienced a local reaction described as a round, swollen area with red discoloration after administering allergenic extract manufactured by Greer, was not investigated.

D. On 03/27/2013, adverse event report # 13-014 that a patient experienced injection site reaction, upper arm pain, erythema, necrotic tissue following administering allergenic extract products manufactured by Greer, was not investigated.

E. On 03/13/2013, adverse event report # 13-011 that patient was unable to bend this thumb following a single injection of allergenic extract manufactured by Greer, was not investigated.


8. The General Safety Test is not performed according to procedures. For example:

A. SOP # QCA008, Safety Test Procedure requires, "(b) (4)". (b) (4) observations are not documented on the (b) (4) checks. The overall facility observation of (b) (4) is documented with an initial and does not differentiate between (b) (4) (b) (4) test.

B. The balance used to weigh (b) (4) for the General Safety Test is not checked with weights in the range of use for the test. The (b) (4) weigh approximate (b) (4) but the checks are performed with (b) (4) weights.

9. Certificates of testing of closures are accepted in lieu of testing without establishing the reliability of the supplier's test results through appropriate validation of the test results at appropriate intervals. Specifically,

A. Your firm does not perform endotoxin, bioburden, or particulate matter testing of your stoppers to periodically validate the supplier's Certificate of Analysis. SOP-QCG02, "Quality Control Sampling and Inspection of Stoppers" only requires (b) (4).

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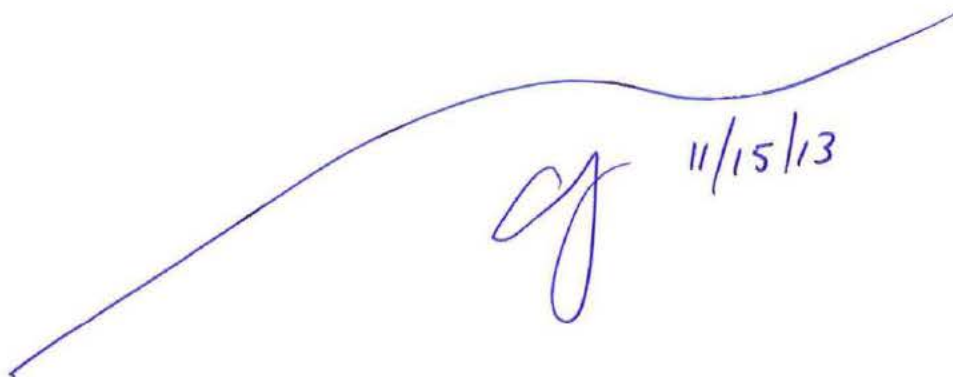
Allergenic Manufacturer

B. Stoppers used with allergenic extracts final product vials and sterile diluents have not been demonstrated not to be reactive, additive, or absorptive. Leachable and extractable studies have not been conducted on 13mm & 20mm West stoppers.

10. Labeled allergenic extract products are not examined during finishing operations to provide assurance that containers in the lot are free of defects and have the correct label. Specifically,

A. The expiration dates are applied to allergenic extract vials just prior to shipment to the customer. The accuracy of the label is not verified prior to shipment. Complaints have been received regarding missing expiration dates.

B. Product is labeled prior to completion of visual inspection activities and thereby preventing a complete view of the contents.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."